REMARKS

The Applicant kindly thanks the Examiner for the interview of October 17, 2007. Per communications on that day the Applicant hereby amends the claims and submits a Declaration under 37 CFR 1.132 herewith to illustrate that drug release profiles achieved by tablets defined by the claims presented herewith cannot be achieved by tablets disclosed and contemplated by Conte in U.S. Patent 4,865,849.

Claims 1-28 are now pending. The Applicant respectfully remove the term "prevention" from the language of the claims (i.e., claims 24-28) to expedite prosecution of this case.

35 USC §§102 and 103 - Conte U.S. 4,865,849 in view of cited disclosures

A. Conte describes, suggests and contemplates a tablet that exhibits a protruding core. **The language of the claims now pending do not encompass embodiments which exhibit a protruding section of the core as disclosed in Conte.**

Chronotherapy tablets of the present invention are provided which comprise **a coating which envelops the core** *and* at least one exposed **release face substantially perpendicular** to the longitudinal axis of the core. The language of the claims now pending does not allow for a protruding section of the core as disclosed in Conte. Indeed, a protruding core, *per se*, (as disclosed by Conte) necessarily allows release of drug from the exposed portions of the core that are not substantially *perpendcular* to the longitudinal axis of the core. The Applicant respectfully directs the Examiner's attention to this limitation of the claims now pending. Moreover, since, chronotherapy tablets of the present invention are manufactures by Compression of Granulations *and* Compression Coating, there can be no protruding section in multilayer tablets made on a multilayer compression machine and coated on a compression coating machine. It is not possible to have a protruding portion when a multilayer tablet is compression coated. Only the face can be left naked, i.e., without coat materials. See, e.g., paragraphs 74, 76, *et seq*, of the instant specification.

The Examiner is respectfully referred to the rule 132 declaration presented herewith. An important feature of the present invention is the ability of the tablets to provide a constant rate of drug release from the release face (receding disc (dm/dt =A(dx/dt)C)). As the

core is covered on all sides and only the circular release face is exposed, the release of drug occurs from this face providing constant rate of drug release at defined intervals.

B. The nature, purpose, and effect of adding pore forming materials to the coat casing chronotherapy tablets of the present invention and Conte's adding polymers soluble in the intestine, are quite different. Conte discloses polymers soluble in alkaline (entro soluble) to allow the polymer to dissolve and release the entrapped drug. The entro soluble polymers usually dissolve within 15 to 6o minutes of arriving in the alkaline medium of the intestine. In sharp contrast, water-soluble pore-forming material(s) substantially leach out of the coat thereby introducing mechanical instability. The coat, however, forms physical pores and disintegrates *after* release of the active compound is complete. The pores, moreover, do not substantially affect the release rate of the active ingredient.[1] The coat remains intact throughout the delivery period but disintegrates prior to evacuation from the colon.

Since none of the claims now pending encompass anything within the disclosure of Conte the subject matter cannot be anticipated as a matter of law. The Applicants respectfully request the Examiner to withdraw all rejections under 35 USC § 102.

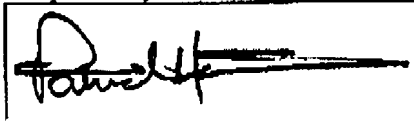
Since none of the claims now pending encompass anything contemplated or suggested by the disclosure of Conte in combination with any of the cited references the subject matter cannot be obvious as a matter of law.[2] The Applicants respectfully request the Examiner to withdraw all rejections under 35 USC § 103.

[1] The Examiner is respectfully referred to paragraph 61, for example, of the specification as filed.

[2] It is axiomatic that a claimed invention is not obvious solely because it is composed of elements that are all individually found in the prior art. The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000).

The Applicants respectfully submit that claims 1-28 are in condition for allowance. Early action toward this end is courteously solicited. The Examiner is kindly encouraged to telephone the undersigned in order to expedite any detail of the prosecution. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 02-4800.

Respectfully submitted,



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